UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS
	Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *The City of New York v. Abbott Labs., et al.* (S.D.N.Y. No. 04-CV-06054) *County of Suffolk v. Abbott Labs., et al.* (E.D.N.Y. No. CV-03-229) *County of Westchester v. Abbott Labs., et al.* (S.D.N.Y. No. 03-CV-6178) *County of Rockland v. Abbott Labs., et al.* (S.D.N.Y. No. 03-CV-7055) *County of Dutchess v. Abbott Labs., et al.* (S.D.N.Y. No. 05-CV-06458) *County of Putnam v. Abbott Labs., et al.* (S.D.N.Y. No. 05-CV-04740) *County of Washington v. Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00408) *County of Rensselaer v. Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00422) *County of Albany v. Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00425)	

[Caption Continues on Next Page]

DEFENDANTS' JOINT MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED CONSOLIDATED COMPLAINT

County of Warren v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00468))
County of Greene v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00474))
County of Saratoga v. Abbott Labs., et al.)
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County of Columbia v. Abbott Labs., et al.)
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(W.D.N.Y. No. 05-CV-06223))
County of Chemung v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06744))
)
AND)
)
County of Nassau v. Abbott Labs., et al.)
(E.D.N.Y. No. 04-CV-5126))
_____)

PRELIMINARY STATEMENT

The Court's April 2, 2007 Memorandum and Order dismissing certain of plaintiffs' claims prompted plaintiffs to request a status conference, which was held on May 16, 2007. At that hearing, the Court labeled the scope of this case "undoable" and discussed with the parties approaches to "winnowing" it down to a manageable size. *See, e.g.*, May 16, 2007 Status Conference Tr. at 5:5-7 & 6:18. In connection with that discussion, plaintiffs were permitted to re-plead claims relating to Federal Upper Limits ("FULs") and to physician-administered drugs ("PADs"), but they were admonished not to do more: "We're not adding new defendants, new drugs, nothing. You've had your time to do that." *Id.* at 45:4-6.

Plaintiffs' First Amended Consolidated Complaint ("Amended Complaint") brazenly disregards the Court's admonition. It adds 3,555 new NDCs representing more than 1,000 new drugs. Moreover, to circumvent the Court's ruling that "[o]nly those drugs for which plaintiffs have alleged greater than the 20-25% mark up between WAC and AWP survive," *see* April 2, 2007 Opinion, at 37 n.9, plaintiffs have changed their method of calculating spreads, without saying so. Plaintiffs now measure the "spread" between AWP and the single lowest transaction price at which any wholesaler sold to any provider (not some average of wholesale prices). This sleight of hand yields spreads of literally millions of percent for numerous drugs, including some shown during the Class 2 and 3 trial in this MDL to have had actual spreads more appropriately measured of less than 30%. This maneuver alone attempts to add back into this case hundreds of drugs that had been dismissed without leave to add them back.[1]

[1] The Amended Complaint includes several counts that were dismissed in their entirety, namely Counts I, II, IV, and V. We assume that plaintiffs have retained these Counts only to preserve their appellate rights and, therefore, we do not address them in this motion, since they have already been dismissed. Similarly, to the extent that the Amended Complaint simply re-pleads allegations relating to Medicaid rebates and Best Price that were previously dismissed for lack of particularity, these allegations should be dismissed again.

At the same time, Plaintiffs' new allegations as to FULs and PADs do not avoid the Court's previous grounds for dismissal and should be dismissed again – this time with prejudice and without leave to re-plead. Plaintiffs' theory is that FULs were supposed to have been based on the lowest price at which subject drugs were sold by any wholesaler to any provider. That theory is inconsistent with the language of the FUL regulation, which bases FULs on "published prices." It is also inconsistent with the history of the FUL regulation, which shows unmistakably that HCFA consciously rejected reimbursement based on provider acquisition costs and instead chose to base reimbursement on "HCFA list prices" – *i.e.*, FULs – which HCFA recognized would yield profits to providers as an incentive for them to participate in the Medicaid program and move them to use generic substitutes for branded drugs.

As to PADs, plaintiffs concede, as they must, that New York does not reimburse these drugs on the basis of AWPs or FULs and, for that reason, PADs do not come within the scope of this action. They include, however, numerous "dual-channel" drugs (drugs that are sometimes administered by physicians and sometimes dispensed by pharmacies) without any allegations that these drugs were actually dispensed by pharmacies and reimbursed on the basis of AWP. Accordingly, the Amended Complaint fails to meet the standard set forth in this Court's prior ruling, and plaintiffs' PAD claims should again be dismissed.

ARGUMENT

I. PLAINTIFFS HAVE ADDED NEW DRUGS AND RE-CALCULATED SPREADS IN DISREGARD OF THE COURT'S PRIOR RULING.

In blatant disregard of this Court's directive to limit their revisions to FULs and PADs, plaintiffs have added allegations to their Amended Complaint as to more than 1,000 entirely new drugs and have revised their method of calculating spreads to add back into this case drugs that were previously dismissed. These unlicensed additions should be dismissed.

A. Plaintiffs Add New Drugs Without Leave.

The Amended Complaint includes drugs that were not the subject of any prior complaint in complete disregard of the Court's admonition that, "We're not adding new defendants, new drugs, nothing." May 16, 2007 Status Conference at 45:4-5.

Specifically, plaintiffs add 3,555 new NDCs, representing more than 1,000 new drugs, to their Amended Complaint. These NDCs had not previously been mentioned in any prior version of the complaint. A list of these entirely new NDCs is attached to the Declaration of Kim B. Nemirow Transmitting Documents Submitted in Support of Defendants' Joint Motion to Dismiss Plaintiffs' First Amended Consolidated Complaint (the "Nemirow Declaration") as Exhibit 1. Given that plaintiffs were not granted leave to make these additions, and leave was clearly required, *see* Fed. R. Civ. P. 15, the additions should be dismissed with prejudice and without leave to re-plead.

Plaintiffs' expansion of the case is even farther reaching than just the addition of some new drugs. The prior complaint in the consolidated counties case actually had two attachments – Exhibit A, which listed drugs purportedly at issue in the case, but did not allege spreads as to those drugs, and Exhibit B, which included spread allegations. In its April 2, 2007 Memorandum and Order, the Court dismissed all NDCs for which plaintiffs did not plead any spread allegations on Rule 9(b) grounds and did not grant plaintiffs leave to re-plead. *See* April 2, 2007 Opinion, at 34-36. Counting those NDCs listed in plaintiffs' Amended Complaint that had previously been dismissed by the Court without leave to re-plead, because they were originally pled without any spread allegations at all, plaintiffs actually seek to add, in total, 6,474 new NDCs to this case. A complete list of the NDCs that plaintiffs seek to add is attached to the Nemirow Declaration as Exhibit 2. Given the lack of leave to re-plead spread allegations for NDCs as to which plaintiffs had previously failed to plead a spread, and the current deficiencies

with plaintiffs' spread allegations, *see infra* Section I.B, the NDCs listed in Exhibit 2 to the Nemirow Declaration should be dismissed from this case.

B. Without Leave, Plaintiffs Have Recalculated Spreads for Branded Drugs.

The Court permitted this action to proceed with "only those [branded] drugs for which the plaintiffs have alleged a spread greater than the 20-25% mark up between WAC and AWP" plus other well-known discounts. *See* April 2, 2007 Opinion, at 37 n.9; May 16, 2007 Status Conference Tr. at 22:8-10. Plaintiffs have attempted to avoid the effect of that limitation by changing the method by which they calculate spreads – resulting in spreads of millions of percent. These new spreads displayed in Exhibit B to the Amended Complaint are misleading as well as beyond what the Court permitted.

First, they are not based on anything that could be considered a "market price." Rather than being measured from an average price of one kind or another, they are instead measured from the single lowest price found in wholesaler records for any transaction with any provider at any point in time.[2] This ignores the Court's earlier rulings on prior AWP complaints that spreads be calculated in "good faith" based on an average of the prices paid by providers.[3]

Plaintiffs have data that would allow them to calculate average prices, but they have chosen not to make those calculations. They have obtained data from the three largest national wholesalers, a compilation of which was provided to the defendants on May 21, 2007, and a

[2] Although plaintiffs do not describe the method that they use for calculating these enormous spreads, it is apparent from the data set forth in Exhibit B to the Amended Complaint and the plaintiffs' court-ordered submission to defendants – samples of which are attached to the Nemirow Declaration as Exhibits 4-7.

[3] Before dismissing the "Suffolk 13" and five other defendants, the Court required Suffolk County to provide all documents upon which it relied in calculating its spread – which was based on the difference between AWP and "what Suffolk believe[d to be] an accurate estimate of the actual average of wholesale prices" – and a more definite statement of its method of calculation. *County of Suffolk* v. *Abbott Labs.*, Docket No. 1115, at 4 (D. Mass. Oct. 26, 2004). When the Court learned that plaintiff's alleged "actual average wholesale prices" were based on a very limited sample of prices and extrapolation, it dismissed the claims. *County of Suffolk* v. *Abbott Labs.*, Docket No. 1482 (D. Mass. April 8, 2005).

sample of which is attached to the Nemirow Declaration as Exhibits 4-7.[4] The data show that there is no single price that providers pay for a drug, but rather that prices vary significantly across wholesalers and classes of trade. In Exhibit B to the Amended Complaint, plaintiffs list only the single lowest price found in the data and label this lowest price "AAC," which presumably means "actual acquisition cost" but it is no such thing. They then calculate "spread" as the difference between this single and unexplained price point and the drug's AWP, with preposterous results.

A self-evidently ridiculous example involves Johnson & Johnson's drug Procrit, for which plaintiffs calculate a spread of 21,369,500% Am. Compl., Ex. B-23. As this Court has found, "the spread for Procrit did not exceed 30% in any year for any of the 15 Procrit NDCs. In fact, most spreads were below 25%." *In re Pharmaceutical Indus. AWP Litig.*, Docket No. 4366, at 165 (D. Mass. June 21, 2007) (hereinafter "6/21/07 Opinion"). Indeed, Dr. Hartman calculated Procrit's "average selling price" in 2003 at $1,696.96 (*see* Pls. Ex. 4109 to MDL class action trial, at Attachment G.3.a), whereas plaintiffs in this case say that Procrit's AAC in 2003 was a penny, $0.01. Am. Compl., Ex. B-23.

Another example of the plaintiffs' distortions involves Schering's Temodar 20 MG capsule (NDC 00085-1244-02). Exhibit B asserts a spread of 441% in 2003 by comparing the AWP of $645.43 to the asserted AAC of $119.37. Am. Compl., Ex. B-35. This is directly at odds with the Court's finding, on the basis of a full record, in the MDL, "regarding Temodar," that "all spreads are below 30% and I therefore find no liability." 6/21/07 Opinion, at 175.

[4] This data is effectively incorporated into the Amended Complaint and, for that reason, is properly considered in connection with defendants' Motion to Dismiss claims in the Amended Complaint. *See, e.g., Jorge* v. *Rumsfeld*, 404 F.3d 556, 558-59 (1st Cir. 2005) (allowing consideration of complete document when portions are relied upon by plaintiffs in their complaint); *Clorox Co. P.R.* v. *Proctor & Gamble Comm'l Co.*, 228 F.3d 24, 32 (1st Cir. 2000) ("the district court appropriately may consider the whole of a document integral to or explicitly relied upon in a complaint, even if that document is not annexed to the complaint.").

Second, the prices on which the alleged spreads are based do not relate to any relevant "market" at all. They instead appear to be the lowest prices reflected in any wholesaler data. Treating them as representative of provider acquisition costs is misleading, and in the case of PADs, it is doubly so: Plaintiffs contend that dual-channel PADs should remain in the case because they might sometimes be dispensed by pharmacies, yet they calculate spreads for these drugs from the lowest prices paid by anyone, including doctors and hospitals, with neither allegations nor logic to suggest that physician and hospital acquisition costs are reasonable proxies for pharmacy acquisition costs.

Third, it is clear that, in many cases, plaintiffs' spread calculations are in fact not based on actual sales at all. Exhibit B shows that for at least 322 NDCs, plaintiffs allege that the AAC was a penny, $0.01. *See* Am. Compl., Ex. B. These pennies are more likely placeholders for charitable contributions than actual prices for sales. Regardless of what they are, their use in calculating spreads obviously distorts the result. Again, Procrit is a good example. Procrit was undoubtedly never sold to anyone for a penny. *See* Pls. Ex. 4109 to MDL class action trial, at Attachment G.3.a. The one cent "price" that plaintiffs use when calculating the spread for Procrit is either a mistake or, more likely, it does not represent a "sale" at all.

Fourth, plaintiffs' spread allegations are inconsistent with their own allegations in prior complaints. For example, the earlier New York City and Suffolk County complaints alleged that Amgen's Epogen®, a brand-name product, had spreads on the order of 23% to 29%. In the Amended Complaint, plaintiffs allege that Epogen's spread in 1998 was 3,428,471%. Am. Compl., Ex. B-4. This is not an isolated example: Exhibit B abounds with drugs that plaintiffs now allege had spread of hundreds of thousands or even millions of percent between AAC and AWP, where before plaintiffs had alleged spreads in the range of 20-25%.

In short, plaintiffs' "new" methodology is so clearly flawed that it must have been designed to evade the Court's prior Order. Accordingly, all of plaintiffs' new spread allegations should be dismissed with prejudice and without leave to re-plead.

II. CLAIMS RELATING TO DRUGS SUBJECT TO FEDERAL UPPER LIMITS SHOULD BE DISMISSED UNDER RULE 12(b)(6) AND *TWOMBLY*.

Plaintiffs now allege that each defendant's failure to report to the national drug pricing compendia the lowest prices at which any wholesaler sold its products to the wholesaler's best customers led to inflated FULs and thus to overpayment for drugs subject to FULs. Am. Compl., ¶ 15. Plaintiffs "illustrate" their claim by comparing the FULs set by CMS to the lowest prices at which any wholesaler sold the drugs to any purchaser in any class of trade. *See id.* at Ex. B.

There is no legal authority for the proposition that defendants had a duty to furnish the national compendia with the prices that the plaintiffs now say form the basis for their FUL claims. The existence of any such obligation is belied by the plain meaning of the FUL regulation and its extensive and clear regulatory history. Moreover, plaintiffs' theory that defendants had a duty to cause to be published the lowest price charged by any wholesaler to any of the wholesaler's customers defies common sense. As plaintiffs' own data show, such pricing varies by wholesaler, customer, and drug. Clearly, a manufacturer would not know every price at which a wholesaler was selling products to each one of the wholesaler's customers. The theory that each manufacturer had a duty to report the lowest price charged by any wholesaler to any customer presumes complete knowledge on the part of every manufacturer of every wholesaler's pricing. Plaintiffs do not allege such knowledge, nor could they.

A. By Law, FULs Are To Be Based On Published Prices, Not Transaction Prices.

FULs are set by CMS on the basis of "published prices." The FUL regulation calls for CMS to establish a FUL for a drug if there are at least three sources of the drug that are rated

"A" (therapeutically equivalent) by the FDA. When this condition is satisfied, the FUL is to be set at 150% of the "published price for the least costly therapeutic equivalent (using all national compendia)." 42 C.F.R. § 447.332(b).

The regulation does not expressly define "published price," as this Court has recognized on many occasions. *Id.*; *see also* May 16, 2007 Status Conference Tr. at 30:18-31:2; 31:21-24. Moreover, CMS does not make publicly available the published price upon which a particular FUL is based. However, three types of prices are generally published by the national compendia: AWP, WAC, and Direct Price ("DP").[5] The "WAC" price is an undiscounted "list price used for invoices between drug manufacturers and wholesalers." *See* Medicaid and Medicare Pricing: Strategy to Determine Market Prices, 15-16 (June 21, 2004). "Direct Price" is the undiscounted list price for sales that a manufacturer makes directly to pharmacies. *See* Am. Compl., ¶ 10. As Plaintiffs' Amended Complaint acknowledges, "AWP" is almost invariably higher than WAC or DP. *Id*. The national compendia do not publish individual transaction prices. In particular, they do not publish the lowest prices at which drugs were available in the market, which plaintiffs now assert defendants were required to supply to the compendia for publication.[6]

The FUL regulations in effect today were promulgated in 1987. The Federal Register entry adopting the final rule is attached to the Nemirow Declaration as Exhibit 3.[7] *See* Medicare

[5] While certain pricing compendia may name these prices slightly differently (*e.g.*, First DataBank refers to WAC as WHN), the prices published in the compendia are generally limited to AWP, WAC and DP.

[6] The pricing compendia do not publish Best Prices or AMPs, either, and until 2005, the compendia did not publish ASPs. ASPs had no legal recognition until 2003, and their precise definition is still evolving. They were not reported even to CMS until 2005 and, therefore, could not have been, before then, a basis for calculating FULs.

[7] Substantial deference – so-called *Seminole Rock* deference – is due the interpretation given a term by the agency that promulgated and enforced the regulation in which it appears. *See S. Shore Hosp. Inc*. v. *Thompson*, 308 F.3d 91, 97 (1st Cir. 2002) (citing *Seminole Rock & Sand Co*., 325 U.S. 410, 414 (1945)). As the First Circuit has recognized, "when a federal agency has promulgated and published a regulation pursuant to its own enabling statute, we review its interpretation of that regulation under a standard *even* '*more deferential* . . . than that afforded under

and Medicaid Programs; Limits on Payments for Drugs, 52 Fed. Reg. 28,648 (July 31, 1987). Beginning in the mid-1970s, Congress attempted to achieve savings across all state Medicaid programs through the formation of a federal "Pharmaceutical Reimbursement Board" ("PRB"), which was charged with setting a federal maximum allocable cost or "MAC" for multi-source drugs based on the lowest price at which the drugs were widely and consistently available. *Id.* at 28,648. HCFA and the states believed that the PRB acted too slowly and, at times, imposed prices either too low or too high for particular regions. *Id*. The stated policy behind the 1987 FUL regulation was to do away with the PRB and to give each state maximum flexibility to determine different reimbursement rates for individual multi-source and "other"[8] drugs – subject only to "aggregate" limits on the total amount of reimbursement at which the federal government would continue to fund the federal portion of the state's Medicaid Plan. *Id.*

In arriving at the FUL program, HCFA expressly rejected the idea that actual acquisition cost would be the basis for calculating FULs. HCFA proposed to the states three alternatives to the MAC system: one used pharmacists' actual acquisition costs as the basis for reimbursement; another was a streamlined version of the MAC process; and the third was what became the FUL. *Id.* at 28,648-50. After receiving comments from state Medicaid agencies, pharmacists, and pharmacy associations, HCFA expressly rejected the first alternative, which would have based reimbursement on actual acquisition costs, "due to the consensus expressed by many state agencies regarding administrative costs and implementation problems." *Id.* at 28,650. Thirty-five of the thirty-nine state Medicaid agencies that commented on the cost-based alternative

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Chevron' to the agency's interpretation of the Statute." *Visiting Nurse Ass'n of North Shore, Inc.* v. *Bullen*, 93 F.3d 997, 1002 (1st Cir. 1996) (emphasis added). The agency's interpretation is decisive unless it is plainly erroneous or inconsistent with the regulation. *Thomas Jefferson Univ.* v. *Shalala*, 512 U.S. 504, 512 (1994).

[8] "Other" drugs are defined in the regulations as (a) single-source drugs (*i.e.*, brands) and (b) multi-source drugs that do not yet have a FUL. *See* 42 C.F.R. § 447.331.

urged its rejection on the ground that "it would be costly from an administrative viewpoint." *Id.* With respect to the MAC proposal, commenters indicated that "the MAC rate setting process would remain time consuming and burdensome" and, therefore, it was also rejected. *Id.*

HCFA thus adopted the FUL program rather than the cost-based or MAC alternatives to meet its goals of efficiency, cost-savings, and flexibility for state Medicaid agencies. *Id.* HCFA decided to provide maximum flexibility by setting the FUL as "an aggregate limit to State spending (but not as a payment method for individual prescriptions)." *Id.* at 28,650 (emphasis added). The concept was that the total reimbursement paid by a State Medicaid Plan for all multi-source drugs during a specified period of time could not exceed the reimbursement amount derived using 150% of the lowest published compendia prices for each of the multi-source drugs reimbursed by the Plan. HCFA ordered that, every year, the states would show through statistical modeling that their programs (which HCFA envisioned would include competitive acquisition programs, state "mini MAC" lists, and other innovations) reimbursed at below the FUL formula. *Id.* at 28,650.

HCFA enacted the FUL with the express recognition that it was "building into our rates for ingredients, a profit margin for pharmacists" that would vary from drug to drug. *Id.* at 28,655 (emphasis added). The rationale behind this approach was simple. HCFA was seeking to lower overall cost by encouraging substitution of generic drugs for brands while at the same time not too severely limiting a state's flexibility to provide access to all Medicaid beneficiaries: "We expressed the hope that States would recognize the advantage of providing pharmacists with an incentive to participate in the Medicaid program and to stimulate pharmacists to engage in prudent purchasing practices and the substitution of lower cost therapeutically equivalent products." *Id.* at 28,656; *see also* Medicare and Medicaid Programs; Limits on Payments for

Drugs, 51 Fed. Reg. 29,560, at 29,562 (Aug. 19, 1986) ("In a State using the [FUL], pharmacists would be encouraged to purchase as prudently as possible because, in addition to the dispensing fee they receive under existing regulations, they would retain the difference between what they pay for the drug product and the upper limit of payment established by HCFA for the particular drug").

In the process of adopting the FUL program, HCFA referred to the FUL as the "HCFA list price" and expressly recognized and approved of the very conduct that plaintiffs now condemn, namely that published prices would "cluster" and that actual prices for generics would be discounted significantly from those published prices that formed the basis for the FULs. Equally important, HCFA recognized that neither the state program, nor the federal government would benefit directly from such discounts – the governmental benefit coming indirectly from an overall cost savings resulting from generic substitution:

> By using the lowest compendia price for a drug as the benchmark for our listed drug rates, the low price supplier may be encouraged to raise its published price to a point just below the next higher price. Other drug wholesalers and manufacturers may tend to lower their published prices so the range of published prices would tend to narrow and cluster around the low end of the price scale . . . . [W]e would suspect that price competition would be carried on in the form of discounts, promotional campaigns and other incentives aimed at the retail pharmacists.
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> Such tactics would work to the advantage of both retail druggists and wholesalers. Retail pharmacists would gain by being able to purchase drugs at prices below the HCFA list price, while wholesalers could gradually push the benchmark price upwards without losing sales . . . . [O]ur policy of using published prices as a basis for determining payment levels may cause wholesalers to invent new ways of offering discounts to the smaller independent retail outlets, thereby expanding the practice of discounting to those outlets and enabling them to have access to less expensive sources of pharmaceuticals. The drawback is that neither State programs nor the Federal Medicaid program will benefit from such reductions in wholesale prices.

52 Fed. Reg. at 28,658 (emphasis added).

Over and over again, the regulatory history acknowledges that published prices do not relate to providers' actual acquisition costs and that states can and should vary providers' profit levels on individual drugs (both above and below the compendia-based FULs) to influence prescribing and dispensing patterns. The following discussion is emblematic:

> States will be free to make payments for individual drugs on any reasonable basis so long as the total payments for each group [multi-source or "other"] do not exceed the aggregate limits on that group. . . . We would not expect a State agency to adopt directly the upper limit methodology as a payment method [for individual drugs] because it does not gear payments to markups to the actual costs of acquiring and dispensing these drugs . . . Since we are not placing maximum payment limits on individual drugs, drugs with high compendia prices could generate extremely high payment levels. Unless an agency's payment methodology assumed otherwise, a Medicaid agency could end up paying inappropriately high rates for some drugs . . . .

Id. at 28,665 (emphasis added). HCFA encouraged the states to do the research to develop their own state "mini-MAC programs" and other devices to insure that the compendia prices did not become the default payment rate on individual drugs. *Id.* at 28,653.

Other states established mini-MAC programs as HCFA envisioned. New York, however, did not. Instead, it adopted the HCFA FUL as the reimbursement rate for each and every individual multi-source drug. Am. Compl., ¶¶ 101-05. As a result, the State and the plaintiff Counties committed themselves to paying what HCFA explicitly warned them in certain instances could be "extremely high payment levels" in relation to providers actual acquisition costs for certain multi-source drugs. *Id.* at 28,665. This was their choice, not anyone's fraud.

B. FUL Regulations Impose No Duty On Manufacturers.

The FUL regulatory regime – its plain language and its manifest intent – directly contradicts plaintiffs' bald allegations (made without any explanation) that the FUL regime imposed on each defendant a duty to furnish to the national pricing compendia the single lowest price at which any wholesaler was selling a particular product to any provider. On this basis

alone, plaintiffs' FUL claim should be dismissed. Plaintiffs fail to plead any circumstances from which the Court could infer a legal obligation on the part of drug manufacturers to report actual prices (let along wholesalers' actual prices) to the compendia. Such a duty certainly does not follow from the plain language of the FUL regulation, nor from its regulatory history, which embraces the idea of price competition based on discounts below the FUL and clearly manifests HCFA's intention to encourage pharmacists to make prudent purchasing decisions by permitting them to retain profits on ingredients. Indeed, the regulation accepts that the FUL will be based on the "list prices" that the compendia publish and that price competition will occur in the market place, carried out through discounting below the published price that forms the basis for the FUL.

This lack of a legal foundation for any duty alone would be sufficient to justify dismissal under Rule 12(b)(6). The fatal flaws in plaintiffs' pleading go far beyond that however. The national pricing compendia do not publish any category of prices that includes transaction prices, much less lowest transaction prices. Moreover, no facts are alleged from which one could reasonably infer that defendants knew, or could have known, all of the prices at which each wholesalers sold products to the wholesaler's customers. Nor do the counties assert that they (or the State of New York State or CMS) actually understood or believed that FULs were based on the lowest actual transaction price in the market. They could not possibly have held this belief.

C. Plaintiffs' Claims Regarding the FUL Should Be Dismissed As Implausible Under *Twombly*.

The Supreme Court recently confronted in *Twombly* the question whether implausible allegations are sufficient to state a claim for relief under the antitrust laws. *Bell Atlantic Corp.* v. *Twombly*, --- S. Ct. ---, 2007 WL 1461066, at *11 (May 21, 2007). The Court in doing so first addressed the standard to be applied on a motion to dismiss and held that an action should be

dismissed when plaintiffs fail to provide "enough facts to state a claim to relief that is plausible on its face." *Id.* at *14 (emphasis added). In so holding, the Court "retired" the oft-cited "no set of facts" language from *Conley* v. *Gibson*, 355 U.S. 41, 45-46 (1957). *Id.* at *11.

In *Twombly*, the plaintiff asserted that the so-called "Baby Bell" phone companies conspired with each other to inhibit competition from local exchange carriers and to avoid competition among themselves. *Twombly*, 2007 WL 1461066 at *4-5. The Court found that each of the defendants had ample reasons to compete vigorously with the new entrants and each other. In fact, the Supreme Court rejected as insufficient to state a claim plaintiff's allegation of collusion based on a newspaper report of a statement by the CEO of one of the defendants to the effect that competition among the Baby Bells would not be "right," *see id.* at *12-13, because it was logically and legally inconsistent with each company's incentive to act independently in furtherance of its own economic self-interest. Thus, the Supreme Court held, the complaint was insufficient to require the defendants to engage in an inevitably burdensome defense against the antitrust allegations, and the case was dismissed. *Id.* at *14.

Plaintiffs' alleged "FUL Fraud" is equally implausible for at least three reasons:

First, a FUL set on the basis of the single lowest price at which a wholesaler sold the drug to any customer, as plaintiffs allege, would result in a reimbursement rate that is well below the average price paid to acquire the drug by significant classes of providers. The data produced by plaintiffs on May 21, 2007 in response to the Court's Order at the May 16, 2007 Status Conference reveals that there is actually a wide range of prices at which providers acquire drugs and that these prices vary by class of trade (*e.g.*, independent pharmacy or physicians/clinics). *See* Exs. 4-7 (to the Nemirow Declaration). However, despite plaintiffs' own data showing that the prices paid by providers vary significantly, Exhibit B to the Amended Complaint lists only

the lowest acquisition price plaintiffs could identify for a particular NDC at any point in time and then asserts "FUL Fraud" whenever this acquisition price is more than 50% below the FUL. *See* Am. Compl., ¶ 15 & Ex. B. Doing so, the data reveals, results in FULs for several drugs that would have been significantly lower than the average price paid by whole classes of trade, including independent pharmacies, to acquire the drugs to be dispensed to Medicaid beneficiaries. Thus, under plaintiffs' theory of liability, a significant number of Medicaid providers would be reimbursed at a rate below their actual acquisition costs. This fact has obvious implications contrary to HCFA's intent in adopting the FUL program, *see supra* Section II.A: widespread losses on Medicaid reimbursement would result in limited access to pharmacy services; and the "profit margins" that HCFA intended to be built into ingredient costs for certain drugs to incentivize generic substitution and reduce cost overall would be gone. Put differently, the data reveal that plaintiffs' theory as to FULs simply does not make sense.

Plaintiffs' data shows that, on any number of occasions, the FULs plaintiffs allege should have been set by CMS are below (and often well below) the average price that plaintiffs say was paid by independent pharmacies or other providers to acquire the drug during the particular period in question. The following are only a few of the examples found in plaintiffs' data:

- Plaintiffs suggest that the FUL for Warrick's albuterol .5 MG/ML solution (NDC 59930-1647-02) should have been $0.43 (150% x $0.29 – the lowest price at which any wholesaler sold to any provider or plaintiffs' "AAC"). The data plaintiffs submitted to defendants on May 21 reveal that the average price paid by the independent pharmacy class of trade during the same time period was $2.81. *Compare* Ex. B-35 (to the Complaint) *with* the highlighted portion of Ex. 4 (to Nemirow Declaration).

- Plaintiffs suggest that the FUL for Par's Ibuprofen 400 mg tablets (NDC 49884-0777-01) should have been $1.33 (150% x $0.89). Plaintiffs' data reveal that the average price paid by non-acute care providers during the same time period was $2.75. *Compare* Ex. B-30 (to the Complaint) *with* the highlighted portion of Ex. 5 (to Nemirow Declaration).

- Plaintiffs suggest that the FUL for Novartis's Fluor-op 0.1% eye drops (NDC 58768-0358-05) should have been $2.99 (150% x $1.99). Plaintiffs' data reveal that the average price paid by independent pharmacies to acquire the eye drops during the same time

period was $10.40. *Compare* Ex. B-28 (to the Complaint) *with* the highlighted portion of Ex. 6 (to Nemirow Declaration).

- Plaintiffs suggest that the FUL for Greenstone's Medroxyprogesterone 10 mg tablets (NDC 59762-3742-02) should have been $3.54 (150% x $2.36). Plaintiffs' data reveal that the average price paid by independent pharmacies during the same time period was $4.75. *Compare* Ex. B-31 (to the Complaint) *with* the highlighted portion of Ex. 7 (to Nemirow Declaration).

Thus, according to plaintiffs' own data, any independent drug store or other provider that purchased one of these drugs at or above the average (or even well below the average) and that was reimbursed at the rate plaintiffs seek to impose would have lost money on every single sale to a Medicaid beneficiary. In short, plaintiffs' own data demonstrate that HCFA could not possibly have intended to base FULs on the single lowest price for a drug available in the marketplace to any class of trade.

Second, plaintiffs' theory that manufacturers were required to report to the national drug pricing compendia the single lowest price at which any wholesaler sold a product to any one of its customers necessarily depends on the proposition that each and every manufacturer had complete information about at what prices wholesalers were selling their products to each of the wholesalers' customers. This proposition is directly at odds with the normal functioning of a market in which participants seek to maximize profits. A wholesaler would have absolutely no incentive to disclose its full range of prices or margins to the drug manufacturers (its suppliers) so that the manufacturers could report them for publication in the national pricing compendia. A wholesaler would know that any customer who purchased product at a price higher than the one it disclosed would, the next time, demand a lower price or seek an alternative source of supply in the price competitive marketplace, and a supplier might seek a piece of that margin for itself. Seeking to maximize profits, the wholesaler would try to disclose nothing about its prices or margins so that it could extract the greatest profit possible from each customer. Plaintiffs'

presumption to the contrary simply makes no sense, and plaintiffs have pled no facts that render plausible a theory that the market for prescription drugs functions differently than a normal, price-competitive, profit-maximizing market.

Plaintiffs have, moreover, alleged no facts (nor could they) from which the Court could infer that defendants were aware, or could have been aware, of each and every price at which a wholesaler sold to the wholesaler's customers. Without complete information, no manufacturer could ever fulfill the duty plaintiffs suggest (without authority or explanation) that defendants had to report the lowest single price for any transaction by any wholesaler. Plaintiffs' theory is, thus, implausible for a second reason.

Third, plaintiffs' allegations regarding defendants' motive for engaging in "FUL Fraud" simply make no sense. Plaintiffs contend that the manufacturers' motive for reporting inflated prices was to win market share from competitors by inducing providers to prescribe one drug over another on the basis of a reimbursement spread. Am. Compl., ¶¶ 24-25. Competing for market share through manipulation of published prices is impossible where all drugs are reimbursed based on one manufacturer's published price. If Manufacturer B reports a $2 price for a generic equivalent to the drug made by Manufacturer A, it would not matter if Manufacturer A reported a price of $5 or $15 or even $25. The FUL would still be $3 (150% of $2), and the spread on Manufacturer A's product would continue to be the difference between $3 and the price at which Manufacturer A's drugs were sold to providers in the marketplace.

In other words, once a FUL is in place, the only way for manufacturers A and B to compete against one another for market share is through price competition. This is exactly what HCFA expected would happen when it adopted the FUL regulations. Price competition is a good thing that should be encouraged – not a bad thing that should be penalized as plaintiffs' theory

seems to suggest. In this context, price competition works to the benefit of the Medicaid agency by incentivizing pharmacy providers to dispense generic products, thus reducing the overall cost to the Medicaid agency of providing prescription drug benefits. Because plaintiffs have no plausible theory upon which "FUL fraud" can be based, their allegations as to FULs should be dismissed.

III. PLAINTIFFS' PAD ALLEGATIONS ARE INSUFFICIENT TO SURVIVE DISMISSAL IN LIGHT OF THIS COURT'S PRIOR RULING.

In its April 2, 2007 decision, this Court recognized the importance of the New York Medicaid statute's providing for the reimbursement of physician-administered drugs on the basis of actual cost. The statute mandates that "for drugs provided by medical practitioners and claimed separately by the practitioners, the actual cost of the drugs to the practitioners" is the basis for reimbursement. N.Y. Soc. Serv. L. § 367-a(9)(a). In light of that mandate, the Court dismissed all "PADs purchased after June 9, 1994," when the statute took effect, because they were not "reimbursed based on AWP." April 2, 2007 Opinion at 38. The Court, moreover, rejected plaintiffs' argument that Medimmune's drug Synagis should remain in the case because it was a dual-channel drug that could be both physician-administered and self-administered. *Id.* To survive dismissal, the Court held, plaintiffs must allege specifically that a subject drug <u>was</u> reimbursed on the basis of AWP, not merely that it <u>could have been</u>. Plaintiffs' amended pleading fails to comply with Court's prior Order in this regard.

Plaintiffs' Amended Complaint tries to blur the bright line that this Court has drawn, asserting that "[*t*]*he label "Physician Administered Drug" has no meaning in the New York Medicaid statutory scheme*." Am. Compl., ¶ 109 (emphasis in original). However, they concede as they must that "drugs provided by medical practitioners and claimed separately by the practitioners" are reimbursed on the basis of actual cost. *Id.* at ¶ 111. Plaintiffs distinguish

between "medical practitioners," on the one hand, and, on the other, "Pharmacy Providers under New York Medicaid," *id.*, which include only "forms of licensed pharmacies." *Id.* at ¶ 107. Putting all of this together, plaintiffs assert claims as to those PADs that are also dispensed by pharmacies, but only when they are dispensed by pharmacies.

As to these dual-channel PADs, the closest plaintiffs come to alleging that they were actually reimbursed on the basis of AWP is their conclusory claim in Paragraph 99 of the Amended Complaint that "[e]very drug listed in Exhibit B to this complaint, regardless of what type of drug it is or what form it takes (i.e. tablet, vial, inhalant, injectible, syringe, solution, etc.) *or whether it could be identified as or labeled 'physician administered'* has been reimbursed by New York Medicaid based on AWP or FUL." *Id.* at ¶ 99 (emphasis in original). The more specific allegations that follow, however, directly contradict this conclusory allegation as it relates to PADs.

In the paragraphs that follow, plaintiffs explain that, at all relevant times, the New York Department of Health has maintained a "List of Medicaid Reimbursable Drugs" by NDC, *id.* at ¶ 100, that "[e]very drug listed in Exhibit B . . . has appeared on this List of Medicaid Reimbursable Drugs," *id.* at ¶ 102, and that the "List of Medicaid Reimbursable Drugs sets forth, for each NDC, [a] 'MRA Cost' (or Maximum Reimbursable Amount Cost) that New York Medicaid will pay," *id.* at ¶ 103, which the Amended Complaint says "has been based upon either the drug's reported AWP or any FUL that was in place." *Id.* at ¶ 104. What follows next is the insufficient allegation that "[a]ny licensed Pharmacy Provider enrolled in the New York Medicaid Program <u>who submits a claim</u> for any drug on the List of Medicaid Reimbursable Drug is reimbursed at the MRA cost." *Id.* ¶ 105 (emphasis added).

The Amended Complaint does not say that any of the PADs listed in Exhibit B actually were dispensed by a Pharmacy Provider (and not administered by a physician) and that some Pharmacy Provider actually submitted a claim that was reimbursed on the basis of AWP. In other words, for the PADs for which plaintiffs attempt to state at claim, the Amended Complaint does not allege that there were any claims paid on the basis of AWP. Rather, it alleges only that, if a Pharmacy Provider had dispensed the drug, the Pharmacy Provider would have been reimbursed on the basis of AWP. No county has alleged that it actually paid for a dual-channel drug that was dispensed by a pharmacy. These allegations are no different whatsoever from the ones that the Court found insufficient to sustain plaintiffs' prior argument with regard to Medimmune's drug Synagis, which this Court dismissed from the case in light of the applicable New York Medicaid statute providing for the reimbursement of physician administered drugs on the basis of actual cost. April 2, 2007 Opinion, at 38. Plaintiffs' PAD allegations, therefore, should be dismissed without leave to re-plead.

CONCLUSION

For all the foregoing reasons, Defendants' Joint Motion to Dismiss should be GRANTED.

Schering-Plough Corporation, Schering Corporation, and Warrick Pharmaceuticals Corporation

By their attorneys,

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Dated: June 22, 2007

CERTIFICATE OF SERVICE

I hereby certify that on June 22, 2007, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ Kim B. Nemirow_____
Kim B. Nemirow